IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN *ex rel.* Cathleen Forney *Plaintiffs* v. MEDTRONIC, INC. *Defendant*.	Civil Action No. 15-cv-6264

RELATOR FORNEY'S OPPOSITION TO MEDTRONIC'S MOTION FOR SUMMARY JUDGMENT BASED ON PUBLIC DISCLOSURE BAR

Medtronic moves for summary judgment on Relator's *qui tam* lawsuit. Dkt. Nos. 64-64-19. Medtronic argues that complaints filed by *qui tam* Relators Burns, Stokes, Doe, Onwezen, and Schroeder constitute public disclosures that bar this Court from adjudicating the Relator's Second Amended Complaint, Dkt. No. 42 (hereinafter "SAC").

Medtronic's motion for summary judgment lacks merit. None of the *qui tam* complaints introduced by Medtronic qualifies as a "public disclosure" under the amended False Claims Act public disclosure bar, which requires the United States to be a party in any civil hearing identified as the "public disclosure" barring suit. 31 U.S. C. §

3730(e)(4)(A)(i). And even if one or more complaints satisfied the statutory prerequisites (which they do not), this Court cannot dismiss Relator Forney's SAC because she meets the statutory criteria to qualify as an "original source" under the amended public disclosure bar, 31 U.S. C. § 3730(e)(4)(B), as interpreted by the Third Circuit in *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294 (3rd Cir. 2016).

BACKGROUND FACTS

In accord with the rules and this Court's policies, Relator is submitting a Statement of Facts (hereinafter "Facts") that disputes certain Medtronic recitations of the fact, and provides substantial additional facts – supported by admissible evidence – that should be considered by this Court in ruling on Medtronic's motion for summary judgment. The Facts demonstrate that the United States was not a party to three of the *qui tam* lawsuits relied upon by Medtronic; and, in the other two *qui tam* lawsuits, was only a party to certain claims raised that had no overlap with Relator Forney's claims. *See* Facts at ¶¶ 56-67. The Facts also demonstrate Relator Forney provided substantial information to the Government prior to the filing of her *qui tam* lawsuit in November 2015. *See* Facts at ¶¶ 81-86. The Facts also demonstrate that Relator Forney never saw the *qui tam* complaints introduced into evidence by Medtronic prior to her filing, but instead relied on exclusively on personal knowledge garnered from sixteen years working at Medtronic, including four years in management. *See* Facts at ¶¶ 72-88.

ARGUMENT

As explained below in Section I, on March 23, 2010, the President signed into law Congressional legislation that radically narrowed the False Claims Act's public

disclosure bar. This amended public disclosure statute governs the resolution of Medtronic's motion for summary judgment,[1] and greatly limited the types of public disclosures that satisfy the statute and constitute a qualified "public disclosure." Most importantly, under the amended statute, in order for a lawsuit to qualify as a public disclosure, the United States must be party. 31 U.S. C. § 3730(e)(4)(A)(i).

As explained in Section II, none of the five complaints submitted by Medtronic qualify as public disclosures. The United States is not a party in three of the *qui tam* lawsuits (filed by Burns/Dkt. Nos. 64-6, Stokes/Dkt. No. 11 and John Does/Dkt. No. 64-16). *See* Facts at ¶¶ 53-55, 68-71; *see also United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294 (3rd Cir. 2016). The United States intervened and became a party in Onwezen (Dkt. No. 64-9) and Schroeder (Dkt. No. 64-13) but only with respect to a wholly different Medtronic fraudulent scheme involving paying cash kickbacks to physicians. *See* Facts at ¶¶ 56-67. Medtronic already paid $23.5 million to settle those Onwezen/Schroeder kickback claims to which the United States was a party. *See* Facts at ¶¶ 60-61, 63-64. The United States declined to intervene the remaining Onwezen and Schroeder claims, which are the claims Medtronic alleges overlap with Relator Forney's claims. Thus, because the United States is not a party to

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[1] Medtronic notes that "[t]he statute of limitations for the FCA is six years, 31 U.S.C. § 3731(b), so the time period at issue in this case could extend back to November 20,2009." Although that may be indeed be a theoretical possibility, Relator is not seeking any damages for any claims filed before March 23, 2019. From the perspective of judicial efficiency, it does not make sense to cause this Court to conduct a full jurisdictional analysis under a different statute for only four months when Relator is able to seek damages for ninety-nine months (April 2010 to July 2018) under the amended statute. Relator waives any right to seek damages for claims filed prior to March 23, 2010. For that reason, only the amended public disclosure bar applies to this case.

those claims, their publication on the record cannot be considered as a statutorily-eligible public disclosure. *See* Facts at ¶¶ 56-67.

As explained in Section III, even assuming for the sake of argument that one or more of Medtronic's submitted *qui tam* complaints actually qualified as a "public disclosure" under the amended public disclosure law, Medtronic did not – and cannot – carry its burden of proving that Relator Forney parasitically relied on those disclosures in filing her own lawsuit. The facts prove quite the opposite: Relator Forney, a 16-year Medtronic employee, is an original source who came forward independent of any disclosure and added materially significant details about Medtronic's ongoing fraudulent schemes. *See* SAC; Facts at ¶¶ 72-88. *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294 (3rd Cir. 2016). This Court should deny Medtronic's motion for summary judgment, and enter a new scheduling order to permit the parties to conclude fact and expert discovery.

I. IN 2010, CONGRESS RADICALLY NARROWED THE PUBLIC DISCLOSURE BAR TO PREVENT DISMISSAL OF *QUI TAMS*.

Medtronic fails to alert the Court to the significance of the amended public disclosure law. Instead, Medtronic relies substantially on jurisprudence apply the prior version of the public disclosure law. *See* Medtronic Brief, Dkt. No. 64-1. But as the Third Circuit has held in *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294 (3rd Cir. 2016), the 2010 amendments radically altered the legal landscape. In considering Medtronic's motion for summary judgment, it is critical that the Court understand the history that led to the 2010 amendments, as that demonstrates that Congress viewed the False Claims Act as a critical tool to combat fraud on the

Government, and wanted to lower the obstacles the judiciary was placing in the way of meritorious *qui tam* relators such as Forney.

A. The Legislative History of the False Claims Act Demonstrates Congressional Intent To Ensure the Filing of *Qui Tams* Lawsuits Is Not Chilled or Stifled by Improper Judicial Dismissals.

Congress has struggled to ensure that knowledgeable corporate insiders such as Relator Forney are incented to continue to file *qui tam* actions and expose ongoing corporate fraud, yet simultaneously discourage "parasitical" relators, *i.e.* persons seeking simply to profit off information in the public domain. The statutory history of False Claims Act's public disclosure bar shows Congress seeking the right balance. As originally enacted in 1863, the False Claims Act contained no public disclosure limitation. Indeed, the Supreme Court held in *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 545-48 (1943) that a relator lacking any independent knowledge of fraud could bring a *qui tam* lawsuit based wholly on information found in the Government's criminal indictment.

To address this problem of parasitical relators such as Marcus, Congress amended the Act in 1943 to deprive the Courts of jurisdiction over any lawsuit if the evidence or information was already in the possession of the United States when the lawsuit was brought. 57 Stat. 608, codified at 31 U.S.C. § 232(C); *see United States v. Pittman*, 151 F.2d 851, 854 (5th Cir. 1945), *cert. denied*, 328 U.S. 843 (1946). This 1943 amendment, however, caused a problem for the United States' fraud enforcement efforts: it effectively ended *qui tam* litigation. *See* H. Rep. No. 97, 111th Cong., 1st Sess. *3 (2009)(noting that after 1943, only about 6-10 qui tam cases were filed each year).

As a result, to address this new problem of lack of *qui tam* filings, in 1986, Congress revised the public disclosure bar, seeking to encourage more *qui tam* filings. Under the 1986 amendment, the public disclosure bar remained jurisdictional, and read as follows: "No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless . . . the person bring the action is an original source of information." And an "original source" was defined as "an individual who had direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B).

After this amendment, as Congress noted, "in virtually all FCA cases" prosecuted by relators, defendants such as Medtronic filed jurisdictional challenges to *qui tam* actions, claiming relators did not qualify as original sources. *See* H.Rep. No. 97, 111th Cong., 1st Sess. *24 (2009). Courts interpreted the jurisdictional bar quite restrictively, dismissing and barring a significant number of *qui tam* lawsuits. *See, e.g., Rockwell Int'l Corp. v. U.S.*, 549 U.S. 457 (2007).

These judicial results were inconsistent with Congressional intent behind the statute. As the Senate Committee on the Judiciary observed in S. Rep. No. 507, 110th Cong., 2d Sess. *22 & n. 80 (2008), "[t]he result of these interpretations has been significant litigation, delays in settling FCA cases with clear violations of law, and regrettably, the dismissal and presumptive barring of meritorious claims brought by qui

tam relators. These decisions have created a chilling effect on relators coming forward with claims . . ."

In 2010, Congress acted to correct this problem of federal courts dismissing *qui tam* lawsuits. Congress stripped the jurisdictional bar completely out of the statute and otherwise greatly lowered the barriers to bringing *qui tam* lawsuits by passing the Patient Protection and Affordable Care Act, Publ. L. No. 111-147, Title X, section 10104 (j)(2), 124 Stat. 901 (Mar. 23, 2010).[2] Now codified at 31 U.S. C. § 3730(e)(4), this new "public disclosure" bar reads as follows:

> (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed –
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> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> (ii) (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit or investigation; or
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
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> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosure to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section."

Id.

Medtronic's motion for summary judgment requires this Court to apply this statutory text to the evidence submitted by Medtronic and Relator. As the statute is not jurisdictional any longer, Medtronic bears the burden of proof with Relator enjoying the

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[2] This statute does not have retroactive effect. *Graham County Soil and Water Conservation District et al. v. United States ex rel. Wilson,* 559 U.S. 280, n.1 (2010).

benefit of any factual inferences. If the moving party is unable to demonstrate the absence of any genuine issue of material fact, summary judgment is not proper and must be denied. *See Celotex Corp., v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); *see Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 247, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)(court cannot make credibility determinations upon summary judgment); and *Harris v. Kellogg Brown & Root Servs. Inc*., 724 F.3d 458, 464 (3d Cir. 2013) (non-moving party Relator is entitled to have all inferences drawn from the facts in her favor).

B. The Amended Statute and Third Circuit Decision in *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries* Controls Resolution of Medtronic's Motion.

This amended "public disclosure" statute already has been interpreted and applied by the Court of Appeals for the Third Circuit in *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 298-99 (3rd Cir. 2016), which provides this Court controlling guidance to rely upon during its analysis of Medtronic's motion. At the outset, the Third Circuit held the new statutory language "has radically changed the 'hurdle" for relators" in three ways. First, in accord with other circuits, the Court held that the new statute is not a jurisdictional statute. *Id*. at 299-300. *See, e.g., United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 810 (11th Cir. 2015); and *United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 916 (4th Cir. 2013) ("It is apparent, however, that the public-disclosure bar is no longer jurisdictional.") The Third Circuit, quoting *Gonzalez v. Thaler*, __ U.S. __, 132 S.Ct. 641, 649, 181 L.Ed.2d 619 (2012), reasoned that the new statutory language allowing the Government to block

dismissal proves that the public disclosure bar is no longer jurisdictional. *United States ex rel. Moore*, 812 F.3d at 300.

Second, the Third Circuit noted that amendment narrowed greatly the types of civil lawsuits that can be considered as "hearings" for purposes of the public disclosure bar. Now, in order for a civil lawsuit to be considered a public disclosure, the United States must be a party to the lawsuit. *United States ex rel. Moore*, 812 F.3d at 299 ("As a result, information that was disclosed in a federal case between private parties no longer constitutes publicly disclosed information.")

Third, the Third Circuit found Congress expanded the definition of "original source." Indeed, a relator need not even possesses direct knowledge to qualify as an original source. *Id*. The Third Circuit explained "[t]he focus now is on what independent knowledge the relator has added to what was publicly disclosed." The Third Circuit also held "[a]lthough no direct legislative history seems to exist, the textual changes alone evince Congress's intent to lower the bar for relators, at least as to some of its components." *Id*.

Medtronic's motion fails to advise this Court of the controlling nature of the amended statutory text and the *Moore* decision. Instead, Medtronic submits as public disclosures five *qui tam* complaints voluntarily dismissed by the involved Relators that do not rise to the statutory level of a "public disclosure," and cobbles together an argument relying primarily on decisions applying the prior statutory text. *See* Medtronic Brief, Dkt. No. 64-1.

II. MEDTRONIC FAILED TO SUBMIT ANY QUALIFIED PUBLIC DISCLOSURE TO SUPPORT ITS MOTION FOR SUMMARY JUDGMENT.

Medtronic's motion fails because Medtronic clearly cannot meet the standard of the new public disclosure bar as interpreted by the Third Circuit in the controlling *Moore* decision. Medtronic's Brief fails to discuss the impact of the new statutory requirement that limits qualified public disclosures to only those civil hearings in which the United States is a party. *See* 31 U.S. C. § 3730(e)(4)(A)(ii). Medtronic relies on three *qui tam* complaints (Burns/Dkt. Nos. 64-6, Stokes/Dkt. No. 11 and John Does/Dkt. No. 64-16) in which the United States declined to intervene. As a result, the United States is clearly not a party to these three *qui tam* lawsuits. *See, e.g., United States ex rel. McGough v. Covington Techs. Co*., 967 F.2d 1391 (9th Cir. 1992); *United States ex rel. Killingsworth v. Northrop Corp*., 25 F3d 715 (9th Cir. 1994).

Although the United States intervened in part in the lawsuits brought by Relators Onwezen (Dkt. No. 64-9) and Schroeder (Dkt. No. 64-13), the United States is a party only to certain claims (termed "Covered Conduct") that do not overlap in any way with the Relator's claims. *Compare* Covered Conduct (Facts at ¶ 60) with SAC (Dkt. No. 42). The claims to which the United States is a party ("Covered Conduct") arose from a different fraudulent scheme undertaken by Medtronic, one involving Medtronic paying physicians kickbacks in cash in connection with certain Studies and Registries. Medtronic already paid $23.5 million to settle these kickback allegations, and nothing in Relator's lawsuit touches on that conduct at all. *See* Facts at ¶¶ 56-67.

In short, Medtronic is seeking to dismiss Relator as barred by the public disclosure law, but Medtronic has failed to submit any evidence of a statutorily-sufficient public disclosure. With all inferences are drawn in Relator's favor, Medtronic has failed to carry its burden of proof. *Harris v. Kellogg Brown & Root Servs. Inc*., 724 F.3d 458, 464 (3d Cir. 2013)

A. Medtronic Cannot Rely on the *Burns, Stokes* and *Doe* Complaints as Qualified Public Disclosures Because The United States Is Not A Party in Those Actions.

Medtronic spills much ink arguing that Burns, Stokes and Doe *qui tam* complaints brought forward the same False Claims Act legal theory and facts as brought forth by Relator Forney. *See* Medtronic Brief, Dkt. No. 64-1. But Medtronic sidesteps the preliminary hurdle that must be overcome before this Court should even review these three *qui tam* complaints: establishing that the United States is a party to these voluntarily-dismissed *qui tams*. Prior to the 2010 amendments, Medtronic's shotgun approach of scouring Pacer for dismissed *qui tams* may have persuaded some courts, but the 2010 amendment limited the scope of civil complaints that could be viewed as public disclosure to a far narrower universe – those civil lawsuits "in which the Government or its agent is a party." Section 31 U.S. C. § 3730(e)(4)(A) (i).

Medtronic's only argument seeking to persuade the Court that the Burns, Stokes, and Doe complaints are "public disclosures" is a single line at page 8 of its Brief. Medtronic asserts that "[s]ince these prior disclosures were all made in unsealed *qui tam* complaints, they qualify as public disclosures under the statute." Medtronic Brief at 8. As authority, Medtronic relies on *United States ex rel. Paranich v. Sorgnard*, 396 F.3d

326, 333 (3d Cir. 2005) and *United States ex rel. Denis v. Medco Health Sols. Inc.*, Civ. No. 11-684-RGA, 2017 WL 4838410, at *5 (D.Del. Oct. 26, 2017).

Medtronic's argument is based on faulty legal analysis because it ignores the text of the amended public disclosure bar. The only type of lawsuit capable of being used as a "public disclosure" is a lawsuit "***in which the Government or its agent is a party***." 31 U.S. C. § 3730(e)(4)(A)(i). But the United States was not a party to the Burns, Stokes or Doe lawsuits. The United States never intervened and became a party in any of these three lawsuits. *See* Facts at ¶¶ 53-55 (Burns) ¶¶ 68-69 (Stokes) and ¶¶ 70-71 (Doe).

Medtronic has not offered any evidence – nor does any evidence exist – that proves the United States was a party in the Burns, Stokes or Doe lawsuits. Extensive and long-standing False Claims Act jurisprudence establishes beyond dispute that the United States cannot be considered a "party" to a qui tam if the United States declines to intervene. *See, e.g., United States ex rel. Eisenstein v. City of New York, New York*, 556 U.S. 928 (2009) (when the United States declines to intervene in a *qui tam*, it is not a party); *United States ex rel. Killingsworth v. Northrop Corp*., 25 F3d 715 (9th Cir. 1994); *see also* Boese, John T, *Civil False Claims and Qui Tam Actions*, Fourth Ed., at 4-12, stating "Logically, the government is not a party in cases where it declines to intervene, because it cannot later enter the case without court approval." Thus, Medtronic cannot rely on declined *qui tams* as public disclosures because the United States was not a party in those lawsuits.

Medtronic cites as authority *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 333 (3d Cir. 2005) but that case was decided five years before Congress amended the public disclosure bar, and has no relevance to the pending dispute. Nor can

Medtronic rely on another district court's decision in *United States ex rel. Denis v. Medco Health Sols. Inc.*, Civ. No. 11-684-RGA, 2017 WL 4838410, at *5 (D. Del. Oct. 26, 2017).

There, the district court conducted two separate analyses to determine if relator cleared both the pre-amendment and post-amendment public disclosure bar. For our purposes, only the district court's post-2010 analysis is relevant. The court found "Schumann and Hunt are federal cases in which the government was a party and, therefore, qualify as public disclosures under the amended statute." That statement is clearly true as to the *Hun*t case, a *qui tam* in which the United States had intervened, *U.S. ex rel. Hunt et al. v. Merck-Medco Managed Care LLC*, No. 00-cv-737 (E.D. Pa. 2003). *See* Dkt. No. 27 dated June 20, 2003, which reflects a notice by the United States of "election to intervene." But based on the docket entries in the *Schumann* case, the United States does not appear to have intervened, which means that complaint cannot qualify as a public disclosure.

Relator Denis, however, apparently failed to dispute the issue, as the district court stated, "[t]he first two elements of the post-2010 public disclosure bar are not in dispute." Thus, Medtronic cannot rely on this case to support its *sub silentio* claim that the United States should be considered a party in a *qui tam* even after the United States files a notice of declination for purposes of applying the new public disclosure bar. Relator there conceded the point, but Relator here does not. Adopting the proposition that the United States should automatically be considered a "party" in a declined *qui tam* clearly runs afoul of the text and the intent of the amended public disclosure bar, and is wholly

inconsistent with the Third Circuit's holding in *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 298-99 (3rd Cir. 2016).

B. The United States Is A Party to *Onwezen* and *Schroeder* Claims About a Wholly Different Medtronic Kickback Scheme That Defrauded the United States of at $23.5 Million.

As to the remaining two complaints – the Onwezen and Schroeder complaints – the United States intervened in part, and declined to intervene in part. *See* Facts at ¶¶ 56-67. Thus, for purposes of the public disclosure analysis conducted by this Court in this pending matter, Medtronic cannot rely on the Onwezen and Schroeder *qui tam* complaints *en toto* as qualifying public disclosures because the United States is not a party to those complaints. But the United States intervened in part and thus is a party to those portions of the complaints, which may be able to be viewed as qualifying public disclosures under the amended public disclosure bar. 31 U.S. C. § 3730(e)(4)(A)(i).

Specifically, the United States partially intervened in the Onwezen and Schroeder complaints against Medtronic and obtained a $23.5 million settlement from Medtronic. The United States set forth clearly the portion of the complaints that the United States joined as a party in the Settlement Agreement:

> "In the course of Medtronic's business, Medtronic conducted a post-market clinical study known as "FLOW" between February 1, 2004 and July 31, 2006; a post-market clinical study known as "TRENDS" between November 1, 2003 and February 28, 2006; a device registry known as "OMNI" between September 1, 2005 and August 31, 2011; and a device registry known as "P3" between March 1, 2004 and April 31, 2006 (collective referred to herein as "the Subject Studies and Registries.") Medtronic used the Subject Studies and Registries as vehicles to pay participating physicians kickbacks to implant Medtronic pacemakers and ICDs. Although Medtronic collected data and information from participating physicians, it knowingly and intentionally used the Subject Studies and Registries as a means of increasing device sales by paying certain targeted physicians to participate in the Subject Studies and Registries, which involved the use

> of select Medtronic pacemakers and ICDs. Each of the Subject Studies and Registries required a new or previously implant of a Medtronic device in each patient. In each case, Medtronic paid each participating physician a fee. The United States further contend that Medtronic, acting through its employees, solicited certain physicians for the Subject Studies and Registries in order to convert their business from a competitor's product and/or persuade the physicians to continue using Medtronic products. As a result of the foregoing conduct, the Untied States alleges that Medtronic caused false or fraudulent claims for pacemakers and ICDs relating to the Subject Studies and Registries to be submitted to Medicare and Medicaid. That conduct is referred to below as the "Covered Conduct."

In its press release announcing Medtronic's payment of $23.5 million to settle the fraud allegations, the Assistant Attorney General for the United States for the Civil Division is quoted as saying, "Patient who rely on their healthcare providers to implant vital medical devices expect that those decisions will be made with the patients' best interests in mind. Kickbacks, like those alleged here, distort sound medical judgments with financial incentives paid for by the taxpayers."

Thus, for purposes of the public disclosure analysis here, the Court needs to consider whether the portions of the Onwezen and Schroeder complaints in which the United States intervened and became a party – namely the complaint allegations speaking to the Covered Conduct described above – publicly disclosed substantially the same fraudulent transactions alleged by Relator Forney in the SAC.

It is crystal clear that the United States, Onwezen and Schroeder recovered funds from Medtronic for a different kickback scheme involving payments for participating in Studies and Registries. This Medtronic kickback scheme does not overlap in any way with the kickback scheme alleged by Relator Forney, whose SAC does not mention FLOW, TRENDS, OMNI, or P3, and does not allege payments for participating in

studies. *See* SAC, Dkt. No. 42. Indeed, Medtronic itself does not argue that Relator made claims about FLOW, TRENDS, OMNI or P3. Medtronic Brief, Dkt. 64-1.

C. Complaints That Are Never Served or Litigated Should Not Be Considered the Equivalent of Civil Hearings.

It is worth noting that none of the *qui tam* complaints relied upon by Medtronic was ever litigated in any way. The Burns *qui tam* complaint was voluntarily dismissed six days after being unsealed without any summons ever being served. *See* Facts at ¶¶ 53-55. The Stokes complaint was voluntarily dismissed while the complaint remained under seal and without any service of summons. It only became public later, after the dismissal. *See* Facts at ¶¶ 68-69. The Doe Complaint was voluntarily dismissed with any service of summons one day after it was unsealed. *See* Facts at ¶¶ 70-71. The Onwezen Complaint was dismissed the very day it was unsealed, as the parties had negotiated a settlement with the United States while the matter remained under seal. *See* Facts at ¶¶ 56-62. The Schroder Complaint was subsumed within the Onwezen settlement, and was also dismissed voluntarily without any further litigation. *See* Facts at ¶¶ 63-67.

In short, each *qui tam* complaint appeared only fleetingly on the public record before it was resolved without any litigation whatsoever. It is an open question whether a civil complaint that was never served and never precipitated any civil hearing can suffice to satisfy the statutory requirement of a "civil hearing." The Third Circuit jurisprudence under the pre-2010 statute that equated civil litigation with civil hearing but did not directly address such issues. *See United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co*., 944 F.2d 1149 (3rd Cir. 1991), *United States ex rel. Dunleavy v. County of Del.*, 123 F.3d 734 (3rd Cir. 1997), *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 333 (3d Cir. 2005). Relator raises this separate

grounds for denial of Medtronic's motion in an excess of caution, as it need not be resolved if the Court finds, as it should, that Medtronic failed to prove the United States was a party to the *qui tam* complaints upon which Medtronic relies.

III. MEDTRONIC FAILS TO ESTABLISH THE FRAUD ALLEGED IN RELATOR'S SAC WAS PUBLICLY DISCLOSED IN THE STOKES AND SCHROEDER COMPLAINTS.

For all the reasons set forth above, Relator Forney contends that Medtronic has failed to bring forward to this Court any evidence that "substantially the same allegations or transactions as alleged in [Forney's lawsuit] were publicly disclosed – (i) in a Federal . . civil . . hearing in which the Government or its agent is a party. . . ." 31 U.S. C. § 3730(e)(4)(A)(i). This Court should deny Medtronic's motion for summary judgment on the grounds that Medtronic failed to prove any public disclosure of the same allegations or transactions made by Relator Forney. Even assuming for the sake of argument, however, that Medtronic's five non-litigated *qui tams* constituted qualifying public disclosures (which they do not), this Court would need to deny Medtronic's motion for summary judgment because Medtronic has not carried its burden of proof that the disclosures disclosed the same fraud alleged by Relator Forney. Nor does Medtronic carry its burden of proving that Relator Forney is not an "original source." 31 U.S. C. § 3730(e)(4)(B). As is demonstrated beyond dispute by the SAC and Facts, Relator Forney, a long-time Medtronic employee, brought to the Government a wealth of information that she obtained wholly independent of the five *qui tam* complaints. This information materially added to the information found in those complaints, and clearly satisfies the controlling standard elucidated by the Third Circuit in *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 307 (3rd Cir.

2016). This Court should deny Medtronic's motion for summary judgment, and enter a new scheduling order.

A. In *Moore*, the Third Circuit Articulated the Analysis That Must Be Used To Determine Whether the Putative Public Disclosure Discloses the Same Fraud as Alleged by Relator Forney.

In *United States ex rel. Moore*, 812 F.3d 294 (3rd Cir. 2016), the Third Circuit overruled the district court's holding that the relator did not qualify as an original source. The Third Circuit first examined and discussed the radical changes made by Congress in the 2010 amendment, and held that defendants fell within the statutory zone because they submitted a government report and media articles. *Id*. at 301. Here, by contrast, Medtronic does not fall within the statutory zone because they have not submitted any qualifying public disclosures.

The Court then analyzed whether relator Moore's qui tam nonetheless should be permitted to proceed because Moore qualified under the statute as an "original source." The statutory text defines "original source" as "an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosure to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S. C. § 3730(e)(4)(B).

The Court explained the first task was to identify the gravamen of the fraud publicly disclosed by the third parties and alleged by the relator and determine if it was the same fraud. Relying on *United States ex rel. Zizic v. Q2Adminstrators, LLC*, 728 F.3d 228, 235-36 (3d Cir. 2013), the Court used the following formula to guide the

analysis: X (misrepresented state of facts) + Y (true state of facts) = Z (fraud). The Court found that Moore and the news media/government report both disclosed the same fraud: namely, the fact that the vessels were not owned by U.S. citizens and not commanded by a U.S. captain but instead were operated by a Korean company named Dongwon. The Court thus concluded the government report/new media publicly disclosed the relator's allegations of fraud.

B. Medtronic Relies on a *Qui Tam* Complaints Filed by Stokes and Schroeder That Do Not Even Disclose the Same Genre of Fraud Disclosed by Relator Forney.

Medtronic's evidentiary submission reveals that two of dismissed *qui tam* complaints do not disclose the same fraud as disclosed by Relator Forney. Relator Forney's SAC discloses specific facts proving Medtronic engaged in a fraudulent schemes to pay kickbacks in the form of free device checks[3] and free practice management consulting.[4] *See* SAC, Dkt. No. 42.

In contrast, the Medtronic fraud revealed by the Stokes complaint concerns Medtronic engaging in a completely different fraudulent scheme, one involving Medtronic employees causing the premature generator depletions, which led to increased need for surgical implants. *See* Dkt. No. 64-11. Relator Forney's SAC does not address that

[3] Relator Forney's SAC also alleges free services provided during implant surgeries. As a result of the Court's decision to limit discovery to a very short time period, Relator needed to narrow the scope of the case in order to complete the necessary discovery. Thus, as is evidenced by the discovery process, Relator intends to seek only damages for kickbacks paid in the form of device checks and consulting services. Relator has conferred with the United States, which does not object to Relator ceasing to prosecute the free labor at implant surgeries.

[4] Medtronic tries to splits this free consulting services kickback claim into three separate parts labeled administrative work, reimbursement and practice management. But in fact, the free consulting often spanned these different topics in the same engagement. See Relator's Exhibit 1 at 87-106, discussing Medtronic's use of the lean sigma consulting approach to deliver free services to referring physicians.

fraudulent scheme in any way. Thus, even if the United States was a party to the Stokes Complaint (which it was not), the Stokes Complaint would not qualify as a public disclosure because there is no overlap between the fraud disclosed by Relator Stokes and the fraud disclosed by Relator Forney.

Similarly, the Medtronic fraud revealed by the Schroeder complaint concerns Medtronic engaging in two fraudulent schemes, neither of which is addressed in the Forney complaint. Relator Schroeder brought forward evidence showing Medtronic engaging in the off-label promotion of its products, namely, promoting them for implant in patients who do not need them. *See* Dkt. 64-13. And of course Relator Schroeder also brought forward evidence showing Medtronic paid cash kickbacks to physicians participating in Studies and Registries. *Id., see also* Facts at ¶¶ 63-67. Relator Forney did not bring forward any evidence regarding Medtronic's misconduct in relation to either of these fraudulent schemes. *See* SAC, Dkt. No. 42. Medtronic tries to evade the clearly irrelevant and non-overlapping nature of the Stokes and Schroeder Complaints by citing to various allegations about the industry that are similar to the industry background included in Relator Forney's SAC. But some overlapping descriptions of the industry do not suffice to satisfy the Third Circuit's test in *Moore*. The overlap must go to the gravamen of the fraudulent scheme.

IV. RELATOR FORNEY QUALIFIES AS AN ORIGINAL SOURCE.

Although Relator does not believe Medtronic's other three putative public disclosures pass the *Moore* test requiring a comparison of the fraud disclosed,[5] that conclusion is a closer call. But even if they do, Medtronic cannot prevail on summary judgment because

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[5] *Compare* SAC, Dkt. No. 42 with Burns/Dkt. Nos. 64-6, Onwezen (Dkt. No. 64-9) and John Does/Dkt. No. 64-16).

Relator Forney qualifies as an "original source" under the new statute, as interpreted by the Third Circuit. It is beyond dispute Relator did not obtain the factual information she gave the Government and set forth in the SAC by reviewing any of the putative public disclosures. Instead, Relator is a management-level "insider" who worked for Medtronic (both in the field and at corporate) for sixteen years, and thereafter continued to work in the industry and interacted with Medtronic field employees. *See* Facts at ¶¶ 72-88. It is also beyond dispute that Relator provided to the Government and included in her SAC material information that "improves the quality" of any information disclosed in Medtronic's putative public disclosures. *United States ex rel. Moore*, 812 F.3d 294 at 306. *See* SAC (Dkt. No. 42); Facts at ¶¶ 72-88. Thus, under the Third Circuit's controlling *Moore* decision, Relator qualifies as an original source. This Court should deny Medtronic's motion for summary judgment, and enter a new scheduling order.

A. The Third Circuit Held the Amended Statutory Text Requires An Entirely New Test To Determine if a Relator Is An Original Source.

As explained above, Medtronic cannot rely on the *qui tam* complaints as public disclosures. *United States ex rel. Moore*, 812 F.3d at 299 ("As a result, information that was disclosed in a federal case between private parties no longer constitutes publicly disclosed information.") But even assuming for the sake of argument the complaints qualified as "public disclosures," Medtronic's brief fails to grapple with the fact that Congress expanded the definition of "original source" in the amended public disclosure bar. Indeed, according to the Third Circuit's *Moore* decision, a relator need not even possesses direct knowledge to qualify as an original source. *Id*. The Court explained "[t]he focus now is on what independent knowledge the relator has added to what was publicly disclosed." The Court held "[a]lthough no direct legislative history seems to

exist, the textual changes alone evince Congress's intent to lower the bar for relators, at least as to some of its components." *Id*.

Because the new standard for "original source" is much lower than in the past, the Third Circuit reversed the district court's finding that Moore did not qualify as an original source. *Id*. at 304. The Court held that the district court had erred by using the pre-2010 jurisprudence to hold the relator's information was not independent because the relator learned it from a civil lawsuit in the public domain and the information was not obscure. The Court held that "the PPACA's new definition of original source requires an entirely different analysis." *Id*. at 305. As a result of the amendment, the analysis must now focus on whether the relator's information "materially adds" to the publicly disclosed information. The Court cited the New Oxford Dictionary, and found that "a relator must contribute significant additional information to that which has been publicly disclosed so as to improve it quality." *Id*. at 306.

In response to defendants' argument that Moore's complaint only added details, but was the same fraud revealed in the disclosures, the Court turned to Rule 9(b) standard for help. The Court held, "[i]n our view, this standard also serves as a helpful benchmark for measuring "materially adds." Specifically, a relator materially adds to the publicly disclosed allegation or transaction of fraud when it contributes information – distinct from what was publicly disclosed – that adds in a significant way to the essential factual background: "the who, what, when, where and how of the events at issue." *Id*. at 307. Based on that analytical approach, the Court reversed the district court, finding that relator Moore was an original source because he contributed "significant, specific details that were not publicly disclosed. . ." *Id*.

Thus, the only question for this Court is whether Relator Forney's allegations are specific enough to survive Rule 9(b) and thus add in a significant way to the "essential factual background." Here, of course, the answer to that question is yes, as this Court has already ruled against Medtronic's second motion to dismiss, which alleged that Relator's SAC did not meet the Rule 9(b) standard. *See* Dkt. No. 52.

B. Relator Forney Qualifies as an Original Source.

Medtronic lacks any evidence to place in dispute the fact that Relator did not review any of the putative public disclosures. Although Medtronic counsel studiously avoided asking the Relator that question during the Relator's deposition, Relator Forney has appended hereto as Relator's Exhibit No. 16 a Declaration in which she declares under oath that she did not see the five *qui tam* complaints until Medtronic filed its motion for summary judgment. *See* Relator's Exhibit No. 16 at ¶ 2.

Medtronic lacks any evidence to dispute that Relator Forney was an independent source of information. *See* Facts at ¶¶ 72-88. Relator Forney is the exact opposite of a "parasitical" relator. Rather, Relator Forney is a management-level "insider" who worked for Medtronic (both in the field and at corporate) for sixteen years, and thereafter continued to work in the industry and interacted with Medtronic field employees. *See* Facts at ¶¶ 72-88.

Indeed, even if were not already law of the case (see Dkt. No. 52), Medtronic also lacks any reasoned basis on which to claim that Relator Forney did not provide "significant, specific details that were not publicly disclosed. . ." *Id.* at 307. Relator Forney's SAC includes names, dates, and details of Medtronic's fraudulent scheme that are nowhere to be found in the putative public disclosures. *See* SAC (Dkt. No. 42); Facts

at ¶¶ 72-88. Relator Forney gave the Government (and later produced to Medtronic) many documents that corroborated her allegations, and provided more specific and significant details about Medtronic's fraudulent practices of providing device checks and practice management consulting at no charge. *See* Facts at ¶¶ 81-85. All of this information clearly goes to the "who, what, where, when and how" of Medtronic's fraudulent scheme to bribe physicians by providing free device checks, and free practice management consulting. *See, e.g*., Relator's Exhibit 17. In sum, Relator Forney's information indisputably "improves the quality" of any information disclosed in Medtronic's putative public disclosures. *United States ex rel. Moore*, 812 F.3d 294 at 306.

Medtronic's Brief does not even argue otherwise. Instead, Medtronic's only argument is found at page 10 of its Brief, where Medtronic argues that the only information Relator provided was allegations that "these practices also occurred in her Eastern Pennsylvania district," citing SAC ¶¶ 49-50. But such a gross mischaracterization of the SAC fails to persuade. Relator Forney's SAC specifically alleged facts about a nationwide scheme – facts that this Court already ruled met the Rule 9(b) standard for specificity.

CONCLUSION

This Court should deny Medtronic's motion for summary judgment. Medtronic failed to come forward with any qualifying public disclosures for the Court's consideration. 31 U.S. C. § 3730(e)(4)(A)(Instead, Medtronic relied on three dismissed qui tam complaint in which the United States was not a party; and two dismissed qui tam complaints in which the United States intervened as to a Medtronic fraudulent kickback

scheme that was wholly different from the Medtronic fraudulent kickback scheme being pursued by Relator. Further, even if Medtronic had come forward with a qualifying public disclosure (which it did not), Relator Forney clearly qualifies as an "original source." Even assuming for the sake of argument the five lawsuits qualified as a statutorily acceptable "public disclosure," Relator Forney's Second Amended Complaint adds materially to the facts regarding the "who, what, when, where and how" of Medtronic's fraudulent schemes, and thus cannot be dismissed. This Court need only apply the statute, 31 U.S. C. § 3730(e)(4)(B), and adhered to the reasoning of the controlling Third Circuit decision in *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294 (3rd Cir. 2016) as grounds to deny Medtronic's motion.

Respectfully submitted by:

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